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Olga M. Franz  
Printed Name

*Olga M. Franz*  
Signature

**PATENT APPLICATION**

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Applicant : Janet M. Hock )  
For : METHOD OF INCREASING BONE ) Corresponding to:  
TOUGHNESS AND STIFFNESS AND ) PCT/US99/18961  
REDUCING FRACTURES ) Filed: 8/19/99  
Docket No. : X11965 )

**PRELIMINARY AMENDMENT**

Assistant Commissioner for Patents

Washington, D. C. 20231

Sir:

Prior to examination, please amend the application as follows:

**In the Specification**

Please amend the specification as follows:

Page 5, line 15, delete text starting with "either" and ending with "compared" and replace with --either 20µg/day PTH or 40µg/day PTH, compared--; and

lines 18 - 19, delete text starting with "either" and ending with "compared" and replace with --either 20µg/day PTH or 40µg/day PTH, compared--.

*N.E.* Page 47, line 7, change "µg/kg/day" to --µg/day--.

**In the Claims**

Cancel claims 1-8 (which were filed in the PCT case during a personal interview on July 20, 2000) without prejudice.

Please insert the following new claims.

Claims 1-8 filed on  
~~PROPOSED CLAIMS FOR DISCUSSION~~ 20 July 2000

Patent University  
all fees  
and  
costs

US Format - Method of Use

1. A method for concurrently reducing the risk of both vertebral and non-vertebral bone fracture in a human subject at risk of or having osteoporosis, said method comprising administering to said subject a parathyroid hormone consisting of amino acid sequence 1-34 of human parathyroid hormone without concurrent administration of an antiresorptive agent other than vitamin D or calcium, in a daily dose of 20  $\mu$ g or 40  $\mu$ g for at least about 12 months, up to 3 years.
2. The method of claim 1 wherein said human subject is at risk of or has osteoporosis arising from an age-related hypogonadal condition.
3. The method of claim 2 wherein said subject human is a postmenopausal woman.
4. The method of claim 1 wherein said daily dose is 20  $\mu$ g.
5. The method of claim 1 wherein said daily dose is administered for at least about 24 months.

US Format - Article of Manufacture

6. An article of manufacture comprising packaging material and a pharmaceutical composition contained within said packaging material, said composition comprising a parathyroid hormone consisting of amino acid sequence 1-34 of human parathyroid and said packaging material comprising printed matter which indicates that said composition is effective for concurrently reducing the risk of both vertebral and non-vertebral bone fracture in a human subject at risk of or having osteoporosis when administered to said subject such that said parathyroid hormone is administered without concurrent administration of an antiresorptive agent other than vitamin D or calcium, in a daily dose of 20  $\mu$ g or 40  $\mu$ g for at least about 12 months, up to 3 years.

~~EPO Format New Use~~

*Send C. K. to  
Air Force  
and  
Company*

7. Use of a parathyroid hormone consisting of amino acid sequence 1-34 of human parathyroid hormone for the manufacture of a medicament for concurrently reducing the risk of both vertebral and non-vertebral bone fracture in a human subject at risk of or having osteoporosis,

wherein said medicament is administered to said subject without concurrent administration of an antiresorptive agent other than vitamin D or calcium,

in a daily dose of 20 µg or 40 µg for at least about 12 months, *up to 3 years*

*according to claim 1*

8. ~~Use of a medicament of claim 1 for the manufacture of an article of manufacture comprising packaging material and said medicament contained within said packaging material, said medicament comprising a parathyroid hormone consisting of amino acid sequence 1-34 of human parathyroid and~~

said packaging material comprising printed matter which indicates that

said medicament is effective for concurrently reducing the risk of both vertebral and non-vertebral bone fracture in a human subject at risk of or having osteoporosis when administered to said subject such that said parathyroid hormone is administered

without concurrent administration of an antiresorptive agent other than vitamin D or calcium,

in a daily dose of 20 µg or 40 µg for at least about 12 months *up to 3 years.*

*Add A1*